S. Little 9-7-95

PATENT
8016/PD-3322

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#10/IDS

In re Application of)
Thomas P. Castellano et al.) Examiner: M. Mendez
Serial No.: 08/208,636)
Filed: March 9, 1994) Group Art Unit: 3306
For: PEN-TYPE INJECTOR WITH A)
MICROPROCESSOR AND BLOOD)
CHARACTERISTIC MONITOR)

Assistant Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT

Dear Sir:

In accordance with 37 C.F.R. §§ 1.56 and 1.97, enclosed is a copy of Form PTO-1449 listing the attached references which might be deemed material to the examination of the above-identified application. The references listed on the attached PTO-1449 forms were disclosed to the applicants by a June 20, 1995 PCT search report and by a third party.

1. References Submitted and Non-English Language References

■ Enclosed is a search report for a counterpart PCT application. The following references were cited (see page 3 of 3). All non-English language references are either described on the attached sheets or include an English language abstract.

■ The other references were cited to the applicant by a third party and are related to drive mechanisms (see pages 1 and 2 of 3). All non-English language references are either described on the attached sheets or include an English language abstract.

☐ The specification incorporates comments on the relevancy of non-English language references.

☐ Set forth below are comments provided by the applicant's home country counsel on the relevancy of non-English language references:

2. ☐ The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office Action on the merits, whichever event occurs last. 37 C.F.R. §1.97(b).

3. ■ The information disclosure statement transmitted herewith is being filed *after* three months of the filing date of this national application or the date of entry of the national stage as set forth in §1.491 in an international application or after the mailing date of the first Office Action on the merits, whichever event occurred last but *before* the mailing date of either:

(1) a final action under §1.113 or

(2) a notice of allowance under §1.311, whichever occurs first.

CERTIFICATION OR FEE

A. Included with this transmittal is

i. ■ a certification (set forth below) in accordance with 37 C.F.R. §1.97(e). (If for any reason the certificate set forth below should be unsatisfactory, the Commissioner is provisionally authorized to charge the $210 fee (37 C.F.R. §1.17(p)) to Deposit Account No. 19-3725. A duplicate copy of this sheet is enclosed.)

OR

ii. ☐ the attached fee set forth in 37 C.F.R. §1.17(p) for submission of an information disclosure statement under §1.97(c). ($210.00).

4. ☐ The information disclosure statement transmitted herewith is being filed *after* a final action under §1.113 or a notice of allowance under §1.311, whichever occurs first, but before, or simultaneously with the payment of the issue fee.

CERTIFICATION, PETITION AND FEE

A. In accordance with the requirements of 37 C.F.R. §1.97(d):

i. Set forth below is a certification as specified in 37 C.F.R. §1.97(e).

ii. Applicant hereby petitions for the consideration of the accompanying information disclosure statement. 37 C.F.R. §1.97(d)(ii).

iii. Applicant submits the petition fee set forth in §1.17(i)(1). ($130.00).

CERTIFICATION
(Required if 3Ai or 4 above is marked)

5. I, the person signing below, certify

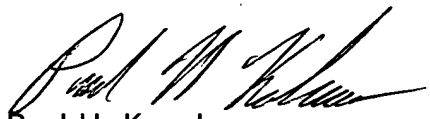
■ that each item of information contained in the information disclosure statement was cited in the attached communication from a foreign patent office in a counterpart foreign application and that the communication is dated not more than three months prior to the filing of the statement. 37 C.F.R. §1.97(e)(1).

AND

■ that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the statement. 37 C.F.R. §1.97(e)(2).

6. ■ If it should be determined that for any reason either an insufficient fee or an excessive fee has been paid, please charge any insufficiency or credit any overpayment necessary to ensure consideration of the information disclosure statement for the above-identified application to Deposit Account No. 19-3725. A duplicate copy of this petition is enclosed.

Respectfully submitted,



Paul H. Kovelman
Registration No. 35,228

Dated: August 16, 1995

SPENSLEY HORN JUBAS & LUBITZ
1880 Century Park East, 5th Floor
Los Angeles, CA 90067
(310) 553-5050

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on 8/16/95.

Paul H. Kovelman (Date)

ATTACHMENT TO INFORMATION DISCLOSURE STATEMENT

I. References Cited in PCT Search Report

US. Patent No. 4,146,029 to Ellinwood, Jr.

8601728 PCT
9213583 PCT
2418642 France
2557445 France
0416975 EPO
93249687 EPO (abstract only)
91225137 EPO (abstract only)

Annual International Conference of the IEEE Engineering in Medicine and Biology Society, "An Optical and RF Telemetry Drug Injection Control and ECG System for Awake Small Animal Studies", Vol. 13, No. 5, 1991.

II. Statement of Relevance for Non-English References Cited in PCT Search Report

French Patent Document No. 2418642 corresponds to Canada Patent Document No. 1103314 and Great Britain Patent Document No. 1574267 provided with this disclosure statement.

III. Statement of Relevance for Non-English References Cited by Third Party

German Patent Document No. 1070784 appears to describe a type of injection mechanism without electronics.

German Patent Document No. 22140 appears to describe a ratchet type syringe without electronics.

French Patent Document No. 1149735 appears to describe a ratchet type syringe without electronics.

The following statements of relevance were provided in an information disclosure statement filed during the prosecution of U.S. Patent No. 4,86,591 which describe many of the foreign language references cited in that application. The applicants in this application repeat these statements here for the benefit of the Examiner and to satisfy the requirements under 37 C.F.R. § 1.98(a)(3). However, it should be understood that these statements should not be regarded as admissions by the applicants, and the applicants have not checked these references for accuracy or correctness:

French Patent No. 1,149,735: This relates to a conventional pawl and ratchet drive mechanism in which the extent of travel of the pawl is limited by

a screw stop mechanism. The teeth of the pawl automatically ride back over the teeth of the ratchet as the pawl is returned to the start position. This device can be pumped. There is no suggestion that the drive should be disengageable.

French Patent No. 1,170,312: This relates to a trigger operated pawl and ratchet mechanism to drive the plunger of a conventional syringe mounted on the mechanism. The pawl automatically rides back over the teeth of the ratchet as the pawl is returned to its start position. This device can be pumped. There is no suggestion that the drive should be disengageable.

French Patent No. 1,445,659: This relates to a pawl and ratchet mechanism for driving a plunger in a syringe in which the travel of the pawl is set by a screw adjust mechanism. The pawl automatically rides back over the teeth of the plunger as it returns to the start position. This device can be pumped. There is no suggestion that the drive should be disengageable.

German Patent No. 730,971: This relates to a conventional pawl and ratchet drive mechanism for a syringe in which the pawl can be disengaged by a stop member carried on a sleeve around the ratchet. The stop member disengages the pawl when the ratchet has reached the forward extreme of its travel so that the ratchet and plunger can be retracted to enable the body of the syringe to be cleaned out and refilled. There is no suggestion that the pawl should be disengaged from the ratchet at any other point during the use of the device. The pawl automatically rides back over the teeth of the ratchet as it returns to the start position so that the device can be pumped.

European Specification No. 0,143,895: This relates to a motor driven syringe in which the motor drives a nut engaging a threaded plunger rod. Rotation of the nut drives the plunger axially. There is no reference to a disengageable drive mechanism. The device is complex and costly and not suitable for carriage upon the person.

European Specification No. 0,037,696: This relates to a syringe with a pawl and ratchet mechanism for driving the plunger. The pawl rides back automatically over the teeth of the ratchet as it is returned to its start position. This device can be pumped. The pawl can be disengaged at either extreme of travel of the plunger to permit the plunger to be retracted into the device when a new cartridge is fitted to the drive mechanism. There is no suggestion that the drive mechanism should be disengageable at any other point during the use of the device.

PCT WO 85/02546: This relates to a syringe which is driven by a stepper motor. There is no reference to a pawl and ratchet drive mechanism and the device is costly and complex.

Swiss No. 293,302: This relates to a syringe drive mechanism in which the plunger has a series of axially spaced radial stops which are engaged by two opposed latch mechanisms. The latch mechanisms are out of register with the ribs on the plunger so that when one latch will engage a stop, the other rides over the top of the next stop. If the first latch is released, the plunger can then be moved until the opposed latch registers with a stop and then prevents further movement of the plunger. The second latch can then be released to allow the plunger to be moved until the first latch registers with the next stop to prevent further movement of the plunger. The drive between the plunger and the piston in the syringe is permanently engaged. Where a user requires more than the minimum dose, it is necessary to repeatedly actuate the latch mechanism for the required number of unit dose to be administered. This creates problems since a user must count and remember the number of times he operates the latch. There is no reference whatsoever to a disengageable pawl and ratchet type drive mechanism.